K082330
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08/11/08
PRIMARY CARE SOLUTIONS, INC.
510(k) SUMMARY

OCT 09 2008

Applicant Name/Address	Primary Care Solutions, Inc. 40420 Free Fall Ave. Zephyrhills, FL 33542
Contact:	Ron Maddix, Vice President & Director of Operations
Telephone: Fax:	813-779-7226 813-715-4084
Trade Name:	Primary Care Solutions Sterile Water and Sterile Saline for Device Irrigation, Moisturizing of Wound Dressings and for use in Jet Lavage for Tissue Debridement Catalog numbers 1500, 1600, 1550, 1650, WF1000 and SF1200
Establishment Reg. No.:	1066336, ISO Certificate No. GB05/66128
Manufacturing Facility:	Primary Care Solutions, Inc. 40420 Free Fall Ave. Zephyrhills, FL 33542
Sterilization Facility:	Food Technology Services, Inc. 502 Prairie Mine Road Mulberry, FL 33860 ISO Cert. #
Classification Name:	Sterile Water and Sterile Saline for Moisturizing a Wound Dressing and for Device Irrigation
Class:	Unclassified
Reason for Application	Expanded Label Usage of Existing Device
Predicate Devices:	K000265, K000266 Sterile Water and Sterile Saline For Device Irrigation, Primary Care Solutions, Inc., 40420 Free Fall Ave., Zephyrhills, FL 33542
Device Description:	This device is USP purified water or saline sealed in 100mL HDPE bottles or 120mL HIPS cups and terminally sterilized using gamma irradiation. All materials are latex free.
Intended Label Expansion:	Moisturizing of Wound Dressings, Device Irrigation and Jet Lavage for Tissue Debridement

Material Comparison to Predicate Device:	There is no material change involved in this notice to expand labeling.
Compliance With Special Controls:	No applicable mandatory performance standards or special controls exist for these devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 09 2008

Primary Care Solutions, Inc.
% Mr. Ronald L. Maddix
VP & Director of Operations
40420 Free Fall Avenue
Zephyrhills, Florida 33542

Re: K082330
Trade/Device Name: Sterile Water & Sterile Saline
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 11, 2008
Received: September 13, 2008

Dear Mr. Maddix:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K082330

Indications for Use

510(k) Number (if known):

Device Name: Sterile Water + Sterile Saline

Indications For Use:

Moisturizing of Wound Dressings, Device Irrigation and Jet Lavage for Tissue Debridement

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark A Millerson

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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